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10/572,404	03/16/2006	Ryuuichi Higuchi	TOYA108.013APC	8010

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EXAMINER
BLAND, LAYLA D

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
08/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/572,404	HIGUCHI ET AL.	
	Examiner	Art Unit	
	LAYLA BLAND	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5, 7, 12, 14, 18-22* is/are pending in the application.

4a) Of the above claim(s) *20-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,7,12,14,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/16/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is a response to Applicant's amendment and declaration of Miyuki Tanaka, submitted May 15, 2008, wherein claims 1-4, 6, 8-11, 13, and 15-17 are canceled, claims 5, 7, 12, 14, 18, and 19 are amended, and new claims 20-22 are added. Claims 5, 7, 12, 14, and 18-22 are pending.

Newly submitted claims 20-22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: newly submitted claims 20-22 are drawn to a method for preparing a drug for improving hyperglycemia, while claims drawn only to a drug for improving hyperglycemia and for a method of treatment using said drug were originally presented. The previously presented inventions and the invention of new claims 20-22 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the technical feature linking the inventions is a drug for improving hyperglycemia, which comprises 9,19-cyclolanostan-3-ol or 24-methylene-9-19-cyclostan-3-ol. As was set forth in the previous office action, both Yongchaiyudha and Abou Zeid teach the administration of one or both of these compounds. Therefore, the technical feature linking the previously presented inventions and the invention of newly submitted claims 20-22 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not definite a contribution over the prior art. Accordingly, the inventions are not so

linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-22 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 5, 7, 12, 14, 18, and 19 are examined on the merits herein.

In view of the cancellation of claims 1-4, 6, 8-11, 13, and 15-17, all rejections made with respect to those claims in the previous office action are withdrawn.

In view of Applicant's amendment submitted May 15, 2008, the rejection of claims 1-18 under 35 USC 101 is withdrawn.

In view of Applicant's amendment and remarks submitted May 15, 2008, the rejection of claims 1-7 and 19 under 35 USC 112, second paragraph, for being indefinite, is withdrawn.

In view of Applicant's amendment submitted May 15, 2008, the rejection of claims 1-19 under 35 USC 112, first paragraph, for scope of enablement, is withdrawn.

In view of Applicant's amendment submitted May 15, 2008, the rejection of claims 4, 5, 11, 12, 17, and 19 under 35 U.S.C. 103(a) as being unpatentable over Abou Zeid, is withdrawn. As amended, the claims require an extract of a plant of the family *Liliaceae*, which is not taught by About Zeid.

In view of Applicant's amendment and remarks submitted May 15, 2008, the rejection of claims 6, 7, 13, and 14 under 35 USC 103(a), as being unpatentable over Abou Zeid in view of Yongchaiyudha, is withdrawn. The claims were previously drawn to a drug, food, or drink which comprised an extract of *Aloe barbadensis Miller* and 0.001-10% by dry mass of a compound of formula I, and the scope of the claims was interpreted to include combinations of extract and compound of formula I. As amended, the claims are drawn to a drug, food, or drink which comprises an extract of *Aloe barbadensis Miller*, which itself must contain 0.001 to 10% by dry mass of 9,19-cyclolanostan-3-ol or 24-methylene-9,19-cyclolanostan-3-ol.

The rejection of claims 1-17 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 11/577/301 is withdrawn because claims 1-19 have been canceled from the copending Application.

The following rejections of record are maintained and modified for relevancy to the amended claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Yongchaiyudha et al. (Phytomedicine Vol. 3 (3), pp. 241-243, 1996, PTO-1449 submitted May 22, 2006) as evidenced by Tanaka et al. (Biol. Pharm. Bull. 29(7) 1418-1422 (2006), of record).

Yongchaiyudha et al. teach that oral administration of one tablespoonful of *Aloe vera* juice twice a day in patients with diabetes resulted in lower blood sugar levels [see abstract]. Aloe gel also produced antihyperglycemic activity in rats which were given one tablespoon twice a day for at least a week [page 241, Introduction]. Various studies of administration of aloe gel up to 20g/kg showed no toxicity [page 241, second column, first paragraph]. For the preparation of *Aloe vera* juice, aloe juice was squeezed from aloe gel and combined with flavors, preservatives, and sweetening agent [page 242, Sample].

Tanaka et al. teach that the following compounds [page 1420, Figure 4] were isolated from Aloe vera gel [see abstract]:

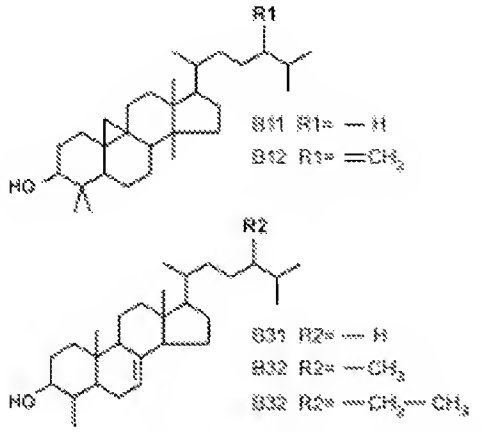


Fig. 4. Chemical Structures of Compounds B11, B12, B31, B32, and B33

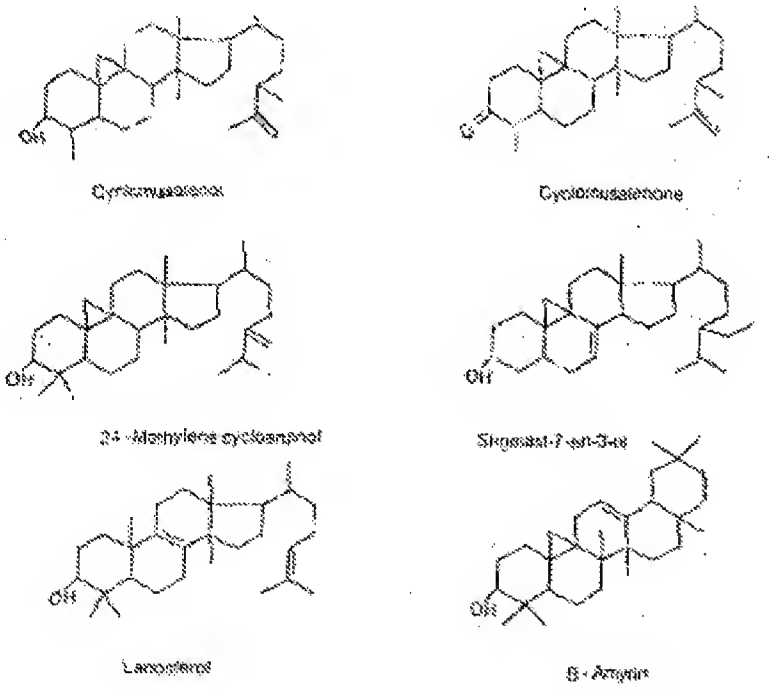
Compound B11 is 9,19-cyclolanostan-3-ol and compound B12 is 24-methylene-9,19-cyclolanostan-3-ol. These compounds are inherently present in *Aloe vera* gel, which was administered to diabetic patients with the result of lower blood sugar levels. Thus, claim 18 is anticipated.

Response to Arguments

Applicant argues that Yongchaiuydha do not teach administration of 9,19-cyclolanostan-3-ol or 24-methylene-9,19-cyclolanostan-3-ol. Yongchaiuydha teaches administration of aloe gel, which inherently contains 9,19-cyclolanostan-3-ol and 24-methylene-9,19-cyclolanostan-3-ol; thus Yongchaiuydha does teach administration of 9,19-cyclolanostan-3-ol and 24-methylene-9,19-cyclolanostan-3-ol.

Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Abou Zeid (Egypt. J. Pharm. Sci. 39, No. 4-6, pp. 379-398 (1998), PTO-1449 submitted March 16, 2006).

Abou Zeid teaches that extracts of *M. cavendishii* and *M. sapientum* have hypoglycemic activity [page 379, third paragraph and page 393, Table 5]. The following compounds, including 24-methylene cycloartanol, [page 392, Figure] were isolated from the hexane extracts of *M. cavendishii* and *M. sapientum* leaves [page 387, second paragraph].



The hexane extract of the leaves was administered to diabetic rats [page 385, III and page 393, Table 5], resulting in at least 50% reduction in blood glucose after one week [page 393, Table 5].

Response to Arguments

Applicant argues that Abou Zeid does not teach that hexane extracts of *M. cavendishii* and *M. sapientum* contained 24-methylene-9,19-cyclolanostan-3-ol in any amount or that 24-methylene-9,19-cyclolanostan-3-ol is the active compound. Abou Zeid teaches that 24-methylene cycloartanol is one of the compounds contained in the hexane extracts of *M. cavendishii* and *M. sapientum* leaves, as discussed above. 24-methylene cycloartanol is the same compound as 24-methylene-9,19-cyclostan-3-ol. Thus, Abou Zeid does teach that the hexane extracts of *M. cavendishii* and *M. sapientum* contained 24-methylene cycloartanol. Abou Zeid need not teach the activity of 24-methylene-9,19-cyclolanostan-3-ol alone to anticipate claim 18, because 24-methylene-9,19-cyclolanostan-3-ol was administered to a subject whose hyperglycemia was to be improved, with the result of improved hyperglycemia. "There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference." See MPEP 2112 II.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5, 7, 12, 14, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yongchaiyudha et al. (Phytomedicine Vol. 3 (3), pp. 241-243, 1996, PTO-1449 submitted May 22, 2006).

Yongchaiyudha et al. teaches as set forth above.

Yongchaiyudha et al. does not teach the concentration of compounds contained within the aloe vera gel or juice. The declaration of Miyuki Tanaka, submitted May 15, 2008, states that the composition of Yongchaiyudha et al. contains 0.000022% of 9,19-cyclolanostan-3-ol and 0.0000016% of 24-methylene-9,19-cyclolanostan-3-ol.

It would have been obvious to one of ordinary skill in the art to increase the concentration of Yongchaiyudha's composition. It is considered well within the skill of the skilled artisan to vary the concentration of Yongchaiyudha's composition, especially in view of the guidance given with regard to effective amounts in humans and in rats. Thus, the claims are obvious over Yongchaiyudha et al.

The claims are drawn to drug, food or drink containing dry aloe vera gel in an amount effective to improve hyperglycemia, comprising 9,19-cyclolanostan-3-ol or -methylene-9,19-cyclolanostan-3-ol, and administration of the drug, food or drink to a subject in need of improved hyperglycemia. Yongchaiyudha et al. teach administration of aloe vera gel in a diluted form, for the same purpose. Applicant admits, via the declaration of Miyuki Tanaka, submitted May 15, 2008, that the aloe vera gel of Yongchaiyudha et al contains 9,19-cyclolanostan-3-ol and -methylene-9,19-cyclolanostan-3-ol, though in lower concentration than is claimed. Thus, Applicant's claimed drug, food, or drink is nothing more than a more concentrated version of what is

already known in the art, and for the same purpose. It is considered within the skill of the skilled artisan to vary the concentration of Yongchaiyudha's composition, especially in view of the guidance given with regard to effective amounts in humans and in rats. Thus, the claims are obvious over Yongchaiyudha et al.

Response to Arguments

Applicant argues that the aloe vera extracts of Yongchaiyudha do not contain 0.001-10% of the recited compounds. The claims are drawn to drug, food or drink containing dry aloe vera gel in an amount effective to improve hyperglycemia, comprising 9,19-cyclolanostan-3-ol or -methylene-9,19-cyclolanostan-3-ol, and administration of the drug, food or drink to a subject in need of improved hyperglycemia. Yongchaiyudha et al. teach administration of aloe vera gel in a diluted form, for the same purpose. Applicant admits, via the declaration of Miyuki Tanaka, submitted May 15, 2008, that the aloe vera gel of Yongchaiyudha et al contains 9,19-cyclolanostan-3-ol and -methylene-9,19-cyclolanostan-3-ol, though in lower concentration than is claimed. Thus, Applicant's claimed drug, food, or drink is nothing more than a more concentrated version of what is already known in the art, and for the same purpose. It is considered within the skill of the skilled artisan to vary the concentration of Yongchaiyudha's composition, especially in view of the guidance given with regard to effective amounts in humans and in rats. Thus, the claims are obvious over Yongchaiyudha et al.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Tuesday - Friday, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623

/Layla Bland/
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